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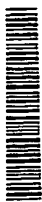
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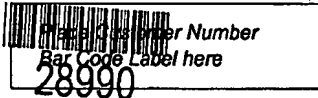
PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

17858 U.S. PTO
60/525315



112603

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<input type="checkbox"/> Additional inventors are being named on the _____ separately numbered sheets attached hereto					
TITLE OF THE INVENTION (280 characters max)					
INJECTOR CONFIGURATION VIA REMOTE INJECTOR REMOTE CONTROL					
Direct all correspondence to: CORRESPONDENCE ADDRESS					
<input checked="" type="checkbox"/> Customer Number		28990			
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ENCLOSED APPLICATION PARTS (check all that apply)					
<input checked="" type="checkbox"/> Specification		Number of Pages		55	<input type="checkbox"/> CD(s), Number
<input checked="" type="checkbox"/> Drawing(s)		Number of Sheets			<input type="checkbox"/> Other (specify)
<input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76					
METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT (check one)					
<input type="checkbox"/> A check or money order is enclosed to cover the filing fees				FILING FEE AMOUNT (\$)	
<input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number		50-1434		\$160.00	
<input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.					
The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.					
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Respectfully submitted

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11/26/03

REGISTRATION NO.

42,062

(if appropriate)

Docket Number:

0008913-0051

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Box Provisional Application, Assistant Commissioner for Patents, Washington, D.C.

P19LARGE/REV05

CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10)Applicant(s): **E-Z-EM Inc.**

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0008913-051

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November 26, 2003

Examiner

TBA

Group Art Unit

TBAInvention: **INJECTOR CONFIGURATION VIA REMOTE INJECTOR REMOTE CONTROL**

I hereby certify that this **Provisional Application For Patent Cover Sheet and Specification 55 pages**
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Brief Summary of Invention:

This invention embodies the idea of utilizing injector electronics hardware and software design as part of the system, to dynamically, create, modify, store and delete operational data and user information on one part of an injector system (injector or remote) using another part of injector system. For instance, in the new release upcoming release of the EMPOWERCTA injector, foreign language displays on the injector head will be downloaded and stored in non-volatile memory or NON-VOLATILE DATA STORAGE MEDIUM from the remote control without having to power the system down. This will permit users to perform dynamic software feature updates to one component of the injector system, namely the injector head without the need to change hardware, update hardware, reprogram with an external programming device.

Novel Features and Advantages:

Some of the novel features and advantages of the Language Update are:

- By the press of a key on an electronic device connected to the system, the user can update the user-displayed messages to various other languages beside English.
- System can display a wide of variety of languages without any hardware modifications to the various components.
- A system previously configured in one language can easily be updated to another language.
- It is broadly contemplated that this medical injector design architecture could be extended to a multitude of user interface elements.

Problems Solved by this Invention:

The main problems solved by this invention are:

- All systems can be configured at one language at factory and set to any language once installed on-site.
- System can be easily updated to add additional languages in the future by updates of software.
- No hardware modifications are required to system to update language.
- Each device of the system can be dynamically updated to a different language via software control.

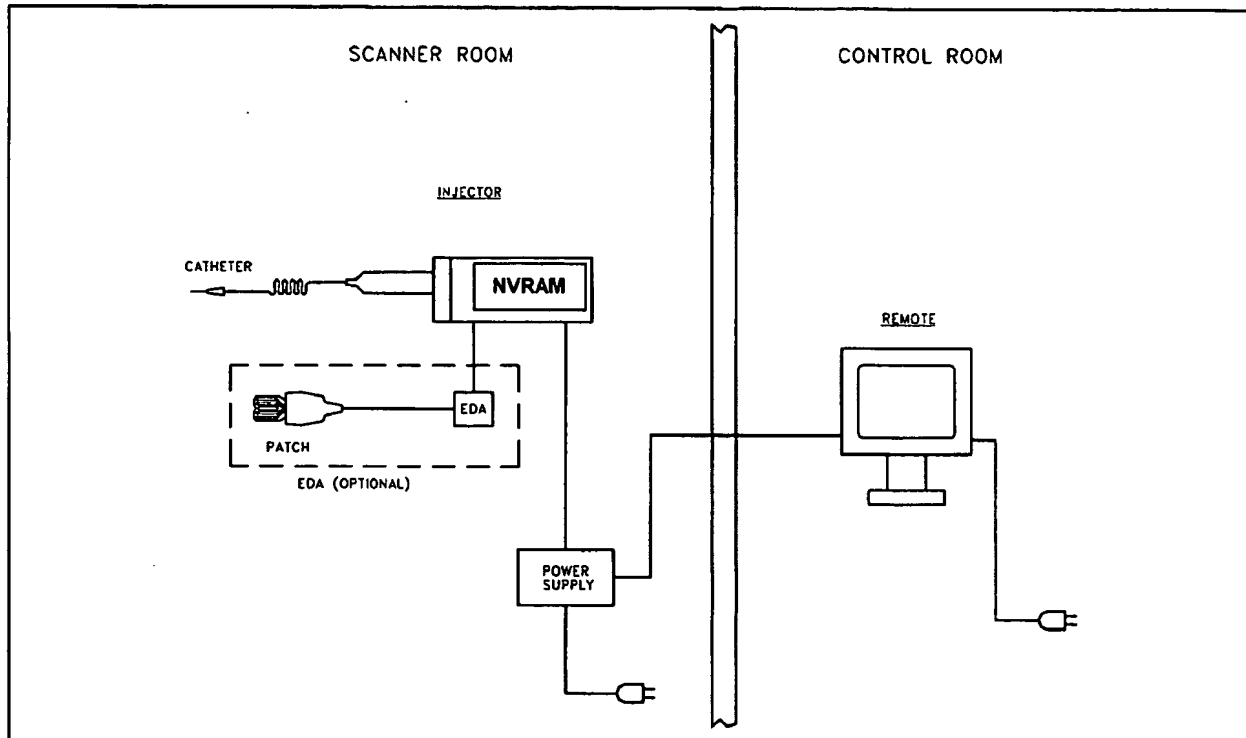
Prior Solutions and their Disadvantages:

Previously, the user would be required to:

- Pre-configure system at factory prior to customer receiving product.
- No electronic display of foreign languages text on the injector head.
- Exchanging "PROM" on each device to a new language
- Limit device to update of messages on Remote Control only and have no displayed messages on Injector or any ancillary device.
- Have key on device that updates the language on that device only.

Detailed Description of the Invention:

The figure below details the typical setup of a CT Injector System. This diagram is used to illustrate how the devices are interconnected. The CT Injector is located in the scanner room. It communicates with the Remote in the control room through a wired link. There is a communication cable routed between the Remote and the power supply. Thereafter a communication/power cable is connected from the power supply to the Injector. Connected to the Injector via cable interconnect is an ancillary device (Extravasation Detection Accessory).



Via the Remote Control, the user can press a Language Selection Key. When pressed, a pop-up window is displayed. The touchscreen window displays the current language and the available languages that the system can display.

Upon touching one of the available Languages, the selected Language is highlighted and the Language Selection window will disappear.

The Remote will access its database and transmit a message to the Injector to update the selected Language.

While the Remote and Injector are updating their languages, the Injector and Remote are unavailable for use. At the conclusion of a successful Language update, the Injector and Remote messages are displayed in the selected language. There is no need to power on or off the system.

The system will remember the latest selected language and upon future power-up will display the messages in the last selected language. The system will have the ability to detect a language mismatch between the Injector and Remote. The user will be prompted with a message to correct this mismatch.

This idea can be used to incorporate the following additional solutions:

- a) The Injector interface also could be used to update the language of the system.
- b) Deployment of Non-Volatile RAM (NVRAM), particularly Flash memory technology to preserve changes should they then be operated independently without a communications link
- c) The communication link between the Injector and Remote could be wireless for purposes of updating NVRAM data.
- d) Other ancillary injector components (For example EDA displayed messages) could be updated via this interface.

References to Other Patient Applications:

To this date, we are not aware of any references, patent applications, or other publications of which are pertinent to this invention.

Proprietary Materials from Outside Sources

To this date, we are not aware of any proprietary materials obtained from an outside vendor that was used to develop this invention.

What we claim

- 1) A medical injection system consisting of an fluid injector component, remote control component and other relevant operational electro-mechanical components in support of medical fluid injection whereby data communications between components exist between components;

wherein one or more of the components of the injection system possesses non-volatile memory whose data can be created, modified, deleted, changed through the user interface by one of the other components of the system for purposes of modifying the user interface, feature set or other visible feature of that part of the system whose NON VOLATILE DATA STORAGE MEDIUM is being modified.

- 2) The medical injector system of claim 1 where software produced user interface messages on the injector head can have their language created, modified or changed in NON VOLATILE DATA STORAGE MEDIUM belonging to injector head via the remote control user interface through the data communication link between injector head and remote control.
- 3) The medical injector system of claim 1 where software produced graphics on the user interface belonging to the injector head can be created, modified or changed in NON VOLATILE DATA STORAGE MEDIUM belonging to the injector via the remote control

user interface through the data communication link between injector head and remote control.

- 4) The medical injector system of claim 1 where software based parameters governing user interface appearance and available features can be created, modified or changed in NON VOLATILE DATA STORAGE MEDIUM belonging to the injector via the remote control user interface through the data communication link between injector head and remote control.
- 5) The medical injector system of claim 1 where software based parameters governing user interface appearance and available features of the component possessing operable NON VOLATILE DATA STORAGE MEDIUM belonging via the user interface of any other component of the injector system through the data communication link between these components.
- 6) The medical injector system of claim 1 where software produced display of syringe pressure on the injector head display can be invoked or removed by data created, modified or changed in NON VOLATILE DATA STORAGE MEDIUM belonging to injector head via the remote control user interface through the data communication link between injector head and remote control, or between the injector head and another component of the injector system.
- 7) The display of syringe pressure on the injector head during an injection.
- 8) The display of injector head syringe pressure on the injector head in claim 7 where pressure is displayed in a continuously updated real time format.
- 9) The display of injector head pressure on the injector in claim 7 where displayed pressure data includes its time history for the duration of the injection.
- 10) The medical injector system of claim 1 where protocol and procedural data as normally defined and limited to the remote control can be created, modified or changed in NON VOLATILE DATA STORAGE MEDIUM belonging to the injector via the remote control user interface through the data communication link between injector head and remote control.
- 11) The injector system of claim 10 where protocol and procedural data can be accessed and by the user through the injector user interface without the remote control being either turned on or connected via data communication to the injector head.
- 12) The injector of claim 10 where the user can administer an injection protocol or procedure through data stored in NON VOLATILE DATA STORAGE MEDIUM in the injector head, within the confines of the injector user interface without the remote control being either turned on, active, or having a connection to the injector head via its data communication path.

The above claims in and of themselves provide the essences of the invention and are not intended to be complete, exhaustive and inclusive of E-Z-EM's utilization of this invention.

Abridged for Invention Disclosure



Visualize a healthier world.

EMPOWERCT Injector System System Specification Document No. 018-9001

Originated by: Bob Williams
Date: May 16, 2000

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REV	DCN#	DESCRIPTION OF CHANGE	DATE	APVD
-	N/A	Initial Release	See above	See above
A	6201	See DCN	02/28/01	SH/RW
B	6215	See DCN	09/05/01	SH/RW
C	6231	See DCN	11/8/01	SH/RW
D	6300	Removed defibrillator proof rating. See pages 4 & 15 for changes	02/06/02	SH/ACH
E	6307	Added "Arming" at the Injector feature	2/28/02	SH/ACH
F	6326	Added new Catalog numbers and software compatibility requirement	5/14/02	SH/ACH
G	6339	Changed Arming timing at Injector to two seconds	6/11/02	SH/GR
H	6349	Added Philips Interconnect Specification	8/2/02	SH/ACH
J	6395	Update Language Selection and add password to Philips Interconnect Selection	2/11/03	SH/ACH
K	6409	Added additional features to system	4/10/03	SH/ACH
L	6450	Added pressure limit unit feature to Remote.	10/10/03	SH/ACH
M	6456	See DCN		

PAGE REVISION TABLE

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4.5.4 Setup Menu Screen

The Setup Menu Screen is used to tailor the system to the user. The Setup Menu Screen can only be accessed through the Main Menu by pressing the SETUP key. The Help Menu System is also available.

4.5.4.1 Inactive Message Display Area

The following Inactive Message Display Area is used to display information that cannot be modified by the user.

System Status Message

The message **"Warning!!! Invalid Service Password. Please try again."** to any incorrect password entered for Service. This message will disappear once the OK key is pressed on the pop-up message area.

When an invalid setting is entered via a pop-up keypad in SETUP, a pop-up message area will display **"Warning!!! Invalid Parameter, Please check allowable range."** This message will disappear once the OK key is pressed on the pop-up message area.

The message **"UNSUCCESSFUL LANGUAGE TRANSMISSION, PLEASE TRY AGAIN"**, if an unsuccessful transmission of the newly selected Language has occurred.

4.5.4.2 Active Input Display Areas

The following Active Input Display Areas are used to display information and can be used to change specific information via pop-up keyboard or keypad.

Date

If this key is pressed, the current setting and format for the date will be displayed. This key will allow the user to change the date, and additionally select the date display format. The default setting is in "MM/DD/YY" format. Once touched, a pop-up numeric keypad will be displayed on the screen that contains the numeric "0-9", "Clear", "Cancel" "Bksp", "Enter", and "Date Display Format" keys.

If the "Date Display Format" key is touched, it will change the display format to "DD/MM/YY". This is a toggle action key changing the date display format between two possible formats. Using the pop-up keypad, the user can enter the new date. Data entered will be checked to determine if the entry is valid after the "Enter" key is pressed. Incorrect entries will prompt the user as described in section 4.5.4.1.

Language Selection

If this key is pressed, a pop-up keypad is displayed. The user is required to enter an alpha/numeric password. Upon successful entry of the password, a pop-up window is opened with the current language being displayed. In addition, the current available languages will be displayed. The default setting is "ENGLISH".

Upon touching one of the available Languages, the selected Language is highlighted and the user has to touch the "Enter" key to complete the selection of the new Language. Once the "Enter" key is touched, the pop-up Language Selection window will disappear.

If the user has selected a new Language, the Remote will go into the Language Update mode. In this mode, the Remote will access its stored Language database. In addition, it will transmit a message to the Injector to update the selected Language. The language selection on the Remote can be performed if there are no communications between the Injector and Remote. The Injector can only be updated if there is successful communications between the Injector and Remote.

While the Remote and Injector are updating their languages, the Injector and Remote are unavailable for use. At the conclusion of a successful Language update, the Injector and Remote messages are displayed in the selected language.

The system will remember the latest selected language and, upon future power-up, will display the messages in the last selected language.

Under the condition that a language mismatch exists between the Injector and Remote, the Remote will alert the user with the message, "Language Mismatch, Select Desired Language". This message will be displayed in both the language selected on the Injector and in the language selected on the Remote. This system cannot be armed until this mismatch is corrected.

PURPOSE:

The purpose of this document is to verify that the EmpowerCT Injector functions as described in section 4.4.2 of the System Specification document No. 018- 9001.

SCOPE:

The procedure described herein applies to the EmpowerCT Injector. This Software Test Plan contains a reasonable set of specific tests designed to validate all of the possible operating configurations of the EmpowerCT Injector while in the STOP mode as described in the System Specification document No. 018- 9001.

DEFINITIONS:

- Single Action Switch – A switch that causes a single action to occur regardless of how long it is depressed/latched.
- N/A – Non-Active; A membrane key is not active when it does not initiate any response from the injector when depressed.
- LOAD Position – The injector is pointed in a direction that is equal to or falls +/-15 degrees from vertical.
- RUN Position – The injector is pointed in a direction that is equal to or lower than 15 degrees below horizontal.

A nominal 100-millisecond tone will sound at the Injector when an active key is pressed unless otherwise specified.

Required Equipment:

Equipment	Quantity
EmpowerCT Injector	1
EmpowerCT Remote	1
EmpowerCT Power Supply Assembly	1
EmpowerCT Communication Cable	1
EDA Test fixture #017-8004	1
CT Fast*Load syringe cat. #6720	1
EmpowerCT Power/Communications Cable	1
EmpowerCT Injector Floor Stand Assembly	1

Test Setup

To perform any of the STOP mode software tests in this test plan, the Injector must be in a known state. This known state will be achieved by completing the following initial setup.

Initial Setup:

1. Connect the cable exiting from the bottom of the injector to the Communications/Power cable.
2. Connect the other end of the Communication/Power Cable to the Power Supply right hand port.
3. Connect one end of the Communications cable to the power supply left hand port and the other end to the back of the Remote.
4. Attach the Pendant switch to the Injector.
5. Connect the EDA Test Fixture # 017-8004 to the EDA module. Put both switches on the test fixture up & set the resistance to 100 ohms.
6. Power-up the Remote and the Injector.

Note:

For software releases 02.04a and higher, the EmpowerCT has incorporated into the system various foreign languages. A table at the end of this document will be utilized for the tester to verify that the various foreign languages messages are correct. During the test steps, the English message followed by the appropriate message number referring to the foreign language table is written for a verification step. Refer to the message number specified and utilize the appropriate column depending on the language being tested.

Following the following steps to test the activate the required foreign language:

1. Verify that the Messages "Injector or Remote Not Found" are not displayed on the Injector or Remote. If message is displayed, check all connections and as required re-power the entire system.
2. Press the SETUP key on the Remote Control.
3. Press the Language Selection key on the Remote Control.
4. Enter the E-Z-EM password to activate the foreign language selection table.
5. Select the appropriate foreign language.
6. Allow the system a few minutes for the software to be updated.
7. Verify that the system is now at the STOP Main Menu in a foreign language.

Software revision being tested: _____

Language Tested: _____

Tests performed by: _____ Date: _____

VERIFICATION OF THE POWER UP SCREEN

This section is to verify the information that is displayed for approximately 5 seconds during the power up sequence.

Turn the Injector off and then on.

Verify that the following information is displayed on the Graphics display of the Injector immediately after being powered on:

Information on the Injector Graphics Display	Initials
The E-Z-EM logo	
The Software Release Identifier	
The Name of the Product	

Verify the following on the Injector during Power-up:

Functions/Information	Initials
No Membrane keys are active	
The display information is displayed for at least five seconds	
After five seconds, the screen is changed to the stop mode screen.	

Section 4.4.2.1 OF SYSTEM SPECIFICATION

Injector Configuration: Tilt Status: LOAD Position

Injector Ram Location: Replace Syringe

Setup:

1. Rotate the Injector to the LOAD position
2. Cycle power to the Injector off and then on.
3. If necessary, place the Injector in the Replace Syringe position by pressing the REPLACE SYRINGE or msg. no. 1 membrane button.

Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	-- ML	
Message Area	PRESS AUTO-INITIALIZE OR MANUAL or msg. no. 2	
Membrane Key 1	Auto-Initialize or msg. no. 3	
Membrane Key 2	N/A	
Membrane Key 3	Manual or msg. no. 4	
Membrane Key 4	N/A	
Membrane Key 5	N/A	

4. ☐ Verify that Membrane Key 1 must be held at least for one second to initiate the AUTO-INITIALIZE function (see Section 4.4.2.2).
5. ☐ Verify while Membrane Key 1 is held at least for one second that there is one short followed by one long acknowledgement tone and then the AUTO-INITIALIZE function is initiated.
6. ☐ Verify that if Membrane Key 1 is held for less than one second the AUTO-INITIALIZE function is not initiated.
7. Press any membrane key to stop the AUTO- INITIALIZE function. If necessary, retract to the Replace syringe position.
8. ☐ Verify that Membrane Key 2 is not active
9. ☐ Verify that Membrane Key 3 places the Injector into MANUAL mode. (See Section 4.4.2.4)
10. Cycle power to the Injector off and then on.
11. ☐ Verify that Membrane Key 4 is not active
12. ☐ Verify that Membrane Key 5 is not active
13. Tilt the Injector out of the LOAD position but not the RUN position.

Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	--- ML	
Message Area	TILT UP TO LOAD or msg. no. 05	
Membrane Key 1-5	N/A	

14. Tilt the Injector to the RUN position.

Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	--- ML	
Message Area	TILT UP TO LOAD or msg. no. 05	
Membrane Key 1-5	N/A	

15. Tilt the Injector to the LOAD position.

Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	--- ML	
Message Area	PRESS AUTO-INITIALIZE OR MANUAL or msg. no. 2	
Membrane Key 1	Auto-Initialize or msg. no. 3	
Membrane Key 2	N/A	
Membrane Key 3	Manual or msg. no. 4	
Membrane Key 4	N/A	
Membrane Key 5	N/A	

16. Use the Injector Hand Knob to advance the Injector ram out of the Replace Syringe position.

Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	--- ML	
Message Area	PRESS AUTO-INITIALIZE OR MANUAL OR REPLACE SYRINGE or msg. no. 6	
Membrane Key 1	Auto-Initialize or msg. no. 3	
Membrane Key 2	N/A	
Membrane Key 3	Manual or msg. no. 4	
Membrane Key 4	N/A	
Membrane Key 5	Replace syringe or msg. no. 01	

17. Use the Injector Hand Knob to retract the Injector ram back to the Replace Syringe position.

Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	--- ML	
Message Area	PRESS AUTO-INITIALIZE OR MANUAL or msg. no. 2	
Membrane Key 1	Auto-Initialize or msg. no. 3	
Membrane Key 2	N/A	
Membrane Key 3	Manual or msg. no. 4	
Membrane Key 4	N/A	
Membrane Key 5	N/A	

Section 4.4.2.2 OF SYSTEM SPECIFICATION

Injector Configuration: Tilt Status: LOAD Position
Injector Ram Location: In Process
Auto- Initialize Invoked

Setup:

1. If not already in this position, place the Injector in the Replace Syringe position by pressing the Replace Syringe membrane button.
2. Press and hold for at least two seconds Membrane Key 1.
3. ☐ Verify that the Auto-Initialize function has been invoked.

Confirm that the following information is displayed:

Graphics Display Area	Displayed information	Initials
Syringe Volume Indicator	--- ML	
Message Area	AUTO-INITIALIZATION IN PROGRESS, PRESS ANY KEY TO STOP or msg. no. 07	
Membrane Keys 1-5	"STOP" or msg. no. 08	

4. ☐ Verify that Membrane Key 1 stops the process and the Syringe Volume displays --- ML.
5. Restart the AUTO-INITIALIZE process by pressing the "AUTO-INITIALIZE" Membrane Key.
6. ☐ Verify that Membrane Key 2 stops the process and the Syringe Volume displays --- ML.
7. Restart the AUTO-INITIALIZE process by pressing the "AUTO- INITIALIZE" or msg. no. 03 Membrane Key.
8. ☐ Verify that Membrane Key 3 stops the process and the Syringe Volume displays --- ML.
9. Restart the AUTO-INITIALIZE process by pressing the "AUTO- INITIALIZE" or msg. no. 03 Membrane Key.
10. ☐ Verify that Membrane Key 4 stops the process and the Syringe Volume displays --- ML.
11. Restart the AUTO-INITIALIZE process by pressing the "AUTO- INITIALIZE" or msg. no. 03 Membrane Key.
12. ☐ Verify that Membrane Key 5 stops the process and the Syringe Volume displays --- ML.
13. Restart the AUTO-INITIALIZE process by pressing the "AUTO- INITIALIZE" or msg. no. 03 Membrane Key.
14. Tilt the Injector out of the LOAD position but not in the RUN position.

15. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	-- ML	
Message Area	TILT UP TO LOAD or msg. no. 05	
Membrane Key 1-5	N/A	

16. ☐ Verify that tilting the Injector out of the LOAD position stops the auto-initialization process.

17. Tilt the Injector to the LOAD position.

18. Restart the AUTO-INITIALIZE process by pressing the "AUTO- INITIALIZE" or msg. no. 03 Membrane Key.

19. Tilt the Injector to the RUN position.

20. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	-- ML	
Message Area	TILT UP TO LOAD or msg. no. 05	
Membrane Key 1-5	N/A	

21. ☐ Verify that tilting the Injector to the RUN position stops the auto-initialization process.

22. Tilt the Injector to the LOAD position.

23. Restart the AUTO-INITIALIZE process by pressing the "AUTO- INITIALIZE" or msg. no. 03 Membrane Key.

24. ☐ Verify that once the system stops when the Injector ram reaches the 0 ml position and the Syringe Volume displays 0 ML.

25. Retract the Injector Ram to the Replace Syringe position. Press the Manual Key. Start the Auto-Initialize process.

Confirm that the initial that the following information is displayed:

Graphics Display Area	Displayed information	Initials
Syringe Volume Indicator	-- ML	
Message Area	AUTO-INITIALIZATION IN PROGRESS, PRESS ANY KEY TO STOP Or msg. no. 07	
Membrane Keys 1-5	"STOP" or msg. no. 08	

Confirm that after five seconds that the following information is displayed:

Graphics Display Area	Displayed information	Initials
Syringe Volume Indicator	XXX ML	
Message Area	AUTO-INITIALIZATION IN PROGRESS, PRESS ANY KEY TO STOP Or msg. no. 07	
Membrane Keys 1-5	"STOP" or msg. no. 08	

26. Tilt the Injector out of the LOAD position.

27. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ML	
Message Area	TILT UP TO LOAD OR TILT DOWN TO RUN or msg. no. 09	
Membrane Key 1-5	N/A	

28. Retract the Injector Ram to the Replace Syringe position. Press the Manual or msg. no. 04 Key and start the auto-initialization process. After the process, immediately starts press any key to stop the process.

29. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	--- ML	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	Auto-Initialize or msg. no. 3	
Membrane Key 2	N/A	
Membrane Key 3	▲	
Membrane Key 4	▲	
Membrane Key 5	Replace syringe or msg. no. 01	

30. Press Membrane Key 1 and start the auto-initialization process. Allow the process to complete.

31. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	0 ML	
Message Area	PRESS AUTO-FILL OR RETRACT TO FILL SYRINGE or msg. no. 10	
Membrane Key 1	AUTO-FILL or msg. no. 11	
Membrane Key 2	N/A	
Membrane Key 3	✓	
Membrane Key 4	✓ ✓	
Membrane Key 5	REPLACE SYRINGE OR MSG. NO. 01	

32. Retract the Injector ram to the Replace syringe position. Press the Manual Key. Start the Auto-Initialization process.

33. When the Injector volume displays XXX ml, press any key to stop the auto-initialization process.

34. Confirm the following is displayed:

Graphics Display Area	Displayed Information	Verify Initials
Syringe Volume Indicator	XXX ml	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	▲	
Membrane Key 2	▲ ▲	
Membrane Key 3	✓	
Membrane Key 4	✓ ✓	
Membrane Key 5	Replace Syringe or msg. no. 01	

35. Retract the Injector Ram to the Replace syringe position. Press the Manual Key. Start the Auto-Initialization process. Immediately as the process begins, tilt the Injector out of the LOAD position.

36. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	-- ML	
Message Area	TILT UP TO LOAD or msg. no. 05	
Membrane Key 1-5	N/A	

37. Tilt the Injector back to the LOAD position.

SECTION 4.4.2.3 of system specification

Injector Configuration: Tilt Status: LOAD Position

Injector Ram Location: Between 0 ml and Replace Syringe Position

System Not Initialized

Setup:

1. If not already in this position, place the Injector in the Replace Syringe position by pressing the REPLACE SYRINGE or msg. no. 01 membrane button.
2. Depress Membrane Key 1 labeled AUTO-INITIALIZE or msg. no. 03
3. Cancel the AUTO-INITIALIZE procedure before 0 ml is reached by pressing any membrane key.
4. ☐ Verify the Injector ram is between 0 ml and the Replace Syringe position.

Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	--- ML	
Message Area	PRESS AUTO-INITIALIZE OR MANUAL OR REPLACE SYRINGE Or msg. no. 06	
Membrane Key 1	Auto-Initialize or msg. no. 03	
Membrane Key 2	N/A	
Membrane Key 3	Manual or msg. no. 04	
Membrane Key 4	N/A	
Membrane Key 5	Replace syringe or msg. no. 01	

5. ☐ Verify that Membrane Key 1 must be held at least for one second to initiate the AUTO-INITIALIZE function (see Section 4.4.2.2).
6. ☐ Verify while Membrane Key 1 is held at least for one second that there is one short followed by one long acknowledgement tone and then the AUTO-INITIALIZE function is initiated.
7. ☐ Verify that if Membrane Key 1 is held for less than one second the AUTO-INITIALIZE function is not initiated.
8. Press any membrane key to stop the AUTO- INITIALIZE function before it reaches the 0 ml position.
9. ☐ Verify that Membrane Key 2 is not active.
10. ☐ Verify that Membrane Key 3 places the Injector into MANUAL mode. (See section 4.4.2.4)
11. Cycle power to the Injector off and then on.
12. ☐ Verify that Membrane Key 4 is not active.

13. ☐ Verify that Membrane Key 5 must be held at least for one second to initiate the REPLACE SYRINGE function (see Section 4.4.2.10).
14. ☐ Verify while Membrane Key 5 is held at least for one second that there is one short followed by one long acknowledgement tone and then the REPLACE SYRINGE function is initiated.
15. ☐ Verify that if Membrane Key 5 is held for less than one second the REPLACE SYRINGE function is not initiated.
16. Press any membrane key to stop the REPLACE SYRINGE function before it reaches the REPLACE SYRINGE position.
17. ☐ Verify that Syringe Volume displays --- ML.
18. Tilt the Injector out of the LOAD position.

19. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	--- ML	
Message Area	TILT UP TO LOAD or msg. no. 05	
Membrane Key 1-5	N/A	

20. Tilt the Injector back to the LOAD position.

21. Tilt the Injector to the RUN position.

22. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	--- ML	
Message Area	TILT UP TO LOAD or msg. no. 05	
Membrane Key 1-5	N/A	

23. Power the Injector off and then on. Tilt the Injector back to the LOAD position.

24. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	--- ML	
Message Area	PRESS AUTO-INITIALIZE OR MANUAL OR REPLACE SYRINGE Or msg. no. 06	
Membrane Key 1	Auto-Initialize or msg. no. 03	
Membrane Key 2	N/A	
Membrane Key 3	Manual or msg. no. 04	
Membrane Key 4	N/A	
Membrane Key 5	Replace syringe or msg. no. 01	

25. Press the Manual Key. Make sure that the syringe is below 200 ml.

26. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	--- ML	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	Auto-Initialize or msg. no. 3	
Membrane Key 2	N/A	
Membrane Key 3	▲	
Membrane Key 4	▲	
Membrane Key 5	Replace syringe or msg. no. 01	

27. Tilt the Injector out of the LOAD position.

28. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	-- ML	
Message Area	TILT UP TO LOAD or msg. no. 05	
Membrane Key 1-5	N/A	

29. Tilt the Injector back to the LOAD position.

30. Tilt the Injector to the RUN position.

31. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	-- ML	
Message Area	TILT UP TO LOAD or msg. no. 05	
Membrane Key 1-5	N/A	

32. Tilt the Injector back to the LOAD position.

33. Use the hand knob to advance the Injector Ram forward till the syringe volume no longer displays --- ml and volume equals 200 ml.

Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Verify
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		Initials
Syringe Volume Indicator	200 ml	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	A	
Membrane Key 2	A A	
Membrane Key 3	N/A	
Membrane Key 4	N/A	
Membrane Key 5	Replace Syringe or msg. no. 01	

34. Retract the Injector to the Replace Syringe position. Press the Manual Key. Press and hold the Slow Forward key for five seconds.

35. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	--- ML	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	Auto-Initialize or msg. no. 3	
Membrane Key 2	N/A	
Membrane Key 3	A	
Membrane Key 4	A A	
Membrane Key 5	Replace syringe or msg. no. 01	

36. Tilt the Injector out of the LOAD position.

37. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	-- ML	
Message Area	TILT UP TO LOAD or msg. no. 05	
Membrane Key 1-5	N/A	

38. Tilt the Injector to the LOAD position.

Section 4.4.2.4 of system specification

Injector Configuration: Tilt Status: LOAD Position

Injector Ram Location: Replace Syringe Position

Manual Key Selected

Setup:

1. If not already in this position, place the Injector in the Replace Syringe position by pressing the Replace Syringe membrane button.

2. Press the MANUAL or msg. no. 04 membrane key.

3. ☐ Verify that the Manual Key or msg. no. 04 is a single action key.

4. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	-- ML	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	Auto-Initialize or msg. no. 03	
Membrane Key 2	N/A	
Membrane Key 3	▲	
Membrane Key 4	N/A	
Membrane Key 5	▲ ▲	

5. ☐ Verify that Membrane Key 1 must be held at least for one second to initiate the AUTO-INITIALIZE function (see Section 4.4.2.2).

6. ☐ Verify while Membrane Key 1 is held at least for one second that there is one short followed by one long acknowledgement tone and then the AUTO-INITIALIZE function is initiated.

7. ☐ Verify that if Membrane Key 1 is held for less than one second the AUTO-INITIALIZE function is not initiated.

8. Press any membrane key to stop the AUTO- INITIALIZE function. Retract back to the Replace syringe and press Manual.

9. ☐ Verify that Membrane Key 2 is not active.

10. Press and hold Membrane Key 3.

11. ☐ Verify that Membrane Key 3 moves the Injector Ram forward at approximately 1 ml/sec.

12. Release Membrane Key 3.

13. ☐ Verify that when Membrane Key 3 is released the Injector Ram stops moving and that the syringe volume displays -- ml.

14. Retract back to the Replace syringe and press Manual.

15. ☐ Verify that Membrane Key 4 is not active.

16. Use the Replace syringe key to return to the Replace Syringe position. Press the Manual key or msg. no. 04 once at the REPLACE SYRINGE position.

17. Press and hold Membrane Key 5 for five seconds.

18. ☐ Verify that Membrane Key 5 moves the Injector Ram forward at approximately 10 ml/sec.

19. Release Membrane Key 5.

20. ☐ Verify that when Membrane Key 5 is released the Injector Ram stops moving.

21. ☐ Verify that the syringe volume displays "XXX" ml where "XXX" is the approximate location of the injector ram.

22. Bring the Injector Ram to the 0 ml position.

23. ☐ Verify that the syringe volume displays 0 ml.

24. Tilt the Injector out of the LOAD position.

25. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	0 ML	
Message Area	TILT UP TO LOAD or msg. no. 05	
Membrane Key 1-5	N/A	

26. Tilt the Injector back to the LOAD position.

27. Tilt the Injector to the RUN position.

28. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	0 ML	
Message Area	TILT UP TO LOAD or msg. no. 05	
Membrane Key 1-5	N/A	

29. Tilt the Injector back to the LOAD position.

30. Bring the Injector Ram back to the Replace Syringe position. Press Membrane Key 3 once. Press Membrane Key 3 for five seconds.

31. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	--- ML	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	Auto-Initialize or msg. no. 03	
Membrane Key 2	N/A	
Membrane Key 3	▲	
Membrane Key 4	▲ ▲	
Membrane Key 5	REPLACE SYRINGE OR MSG. NO. 01	

32. Press and hold Membrane Key 1 until the Injector Ram reaches the 0 ml position.

33. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	0 ML	
Message Area	PRESS AUTO-FILL OR RETRACT TO FILL SYRINGE or msg. no. 10	
Membrane Key 1	AUTO-FILL or msg. no. 11	
Membrane Key 2	N/A	
Membrane Key 3	▼	
Membrane Key 4	▼ ▼	
Membrane Key 5	REPLACE SYRINGE OR MSG. NO. 01	

34. Press the Replace Syringe key. Allow the Injector Ram to retract to the Replace Syringe position. Press the Manual Key.

35. Press Membrane Key 5 until the Injector displays XXX ml.

36. Confirm the following is displayed:

Graphics Display Area	Displayed Information	Verify Initials
Syringe Volume Indicator	XXX ml	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	▲	
Membrane Key 2	▲ ▲	
Membrane Key 3	▼	
Membrane Key 4	▼ ▼	
Membrane Key 5	Replace Syringe or msg. no. 01	

SECTION 4.4.2.5 of system specification (SEE SECTION 4.4.2.9)

Section 4.4.2.6 OF SYSTEM SPECIFICATION

Injector Configuration: Tilt Status: LOAD Position
Injector Ram Location: 0 ML

Setup:

1. If necessary, move the Injector Ram to the 0 ML position.

Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	0 ML	
Message Area	PRESS AUTO-FILL OR RETRACT TO FILL SYRINGE or msg. no. 10	
Membrane Key 1	AUTO-FILL or msg. no. 11	
Membrane Key 2	N/A	
Membrane Key 3	▼	
Membrane Key 4	▼ ▼	
Membrane Key 5	REPLACE SYRINGE or msg. no. 01	

3. ☐ Verify that Membrane Key 1 activates the AUTO- FILL screen and is a single action key (see section 4.4.2.7).
4. Press CANCEL or msg. no. 15 to return to the previous screen
5. ☐ Verify that Membrane Key 2 is not active.
6. Press and hold Membrane Key 3.
7. ☐ Verify that Membrane Key 3 moves the Injector Ram reverse at approximately 0.5 ml/sec.
8. Release Membrane Key 3.
9. ☐ Verify that when Membrane Key 3 is released the Injector Ram stops moving.
10. Return the Injector Ram to the 0 ML position.
11. Press and hold Membrane Key 4.
12. ☐ Verify that Membrane Key 4 moves the Injector Ram reverse at approximately 10 ml/sec.
13. Release Membrane Key 4.
14. ☐ Verify that when Membrane Key 4 is released the Injector Ram stops moving.
15. Return the Injector Ram to the 0 ML position.

16. ☐ Verify that Membrane Key 5 must be held at least for one second to initiate the REPLACE SYRINGE function (see Section 4.4.2.10).

17. ☐ Verify while Membrane Key 5 is held at least for one second that there is one short followed by one long acknowledgement tone and then the REPLACE SYRINGE function is initiated.

18. ☐ Verify that if Membrane Key 5 is held for less than one second the REPLACE SYRINGE function is not initiated.

19. Return the Injector Ram to the 0 ML position.

20. Tilt the Injector out of the LOAD position.

21. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	0 ML	
Message Area	TILT UP TO LOAD or msg. no. 05	
Membrane Key 1-5	N/A	

22. Tilt the Injector back to the LOAD position.

23. Tilt the Injector to the RUN position.

24. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	0 ML	
Message Area	TILT UP TO LOAD or msg. no. 05	
Membrane Key 1-5	N/A	

25. Tilt the Injector back to the LOAD position. Cycle power on the Injector off and then on.

26. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	0 ML	
Message Area	PRESS AUTO-FILL OR RETRACT TO FILL SYRINGE or msg. no. 10	
Membrane Key 1	AUTO-FILL or msg. no. 11	
Membrane Key 2	N/A	
Membrane Key 3	✓	
Membrane Key 4	✓ ✓	
Membrane Key 5	REPLACE SYRINGE or msg. no. 01	

SECTION 4.4.2.7 of system specification

Injector Configuration: Tilt Status: LOAD Position
Injector Ram Location: 0 ML
AUTO-FILL selected

Setup:

1. If necessary, move the Injector Ram to the 0 ML position.
2. Press the AUTO- FILL Key once.

Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	0 ML	
Message Area	FILL VOL.=XXX ML PRESS + 5 OR + 25 TO INCREMENT. PRESS BEGIN AUTO-FILL TO START or msg. no. 13	
Membrane Key 1	+25	
Membrane Key 2	+5	
Membrane Key 3	-5	
Membrane Key 4	BEGIN FILL or msg. no. 14	
Membrane Key 5	CANCEL or msg. no. 15	

3. Press Membrane Key 1.
4. ☐ Verify that Membrane Key 1 changes the AUTO- FILL volume as displayed to 50 ml and acts as a single action key.
5. Press Membrane Key 1 a total seven more times.
6. ☐ Verify that Membrane Key 1 changes the AUTO- FILL volume increments 25 ml per key press and it acts as a single action key and after the seventh key press the auto-fill volume is equal to 25 ml.
7. Press Membrane Key 2.
8. ☐ Verify that Membrane Key 2 increments the auto-fill volume by 5 ml for every key press.
9. Press Membrane Key 3.
10. ☐ Verify that Membrane Key 3 decrements the auto-fill volume by 5 ml for every key press.
11. Press Membrane Key 5.
12. ☐ Verify that Membrane Key 5 returns to the 0 ML position screen.
13. Press the Auto-Fill or msg. no. 11 key.
14. Tilt the Injector out of the LOAD position.

15. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	0 ML	
Message Area	TILT UP TO LOAD or msg. no. 05	
Membrane Key 1-5	N/A	

16. Tilt the Injector back to the LOAD position.

17. Tilt the Injector to the RUN position.

18. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	0 ML	
Message Area	TILT UP TO LOAD or msg. no. 05	
Membrane Key 1-5	N/A	

19. Tilt the Injector back to the LOAD position.

20. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	0 ML	
Message Area	PRESS AUTO-FILL OR RETRACT TO FILL SYRINGE or msg. no. 10	
Membrane Key 1	AUTO-FILL or msg. no. 11	
Membrane Key 2	N/A	
Membrane Key 3	✓	
Membrane Key 4	✓	
Membrane Key 5	REPLACE SYRINGE or msg. no. 01	

21. Press Membrane Key 1. Press Membrane Key 4.

22. ☐ Verify that Membrane Key 4 begins the AUTO- FILL function and fills the syringe to the selected fill volume (see section 4.4.2.8).

Section 4.4.2.8 of system specification

Injector Configuration: Tilt Status: LOAD Position
Injector Ram Location: 0 ML
AUTO-FILL invoked

Setup:

1. Move the Injector Ram to the 0 ML position.
2. Press the AUTO- FILL Membrane Key once to invoke the AUTO- FILL screen.
3. Invoke the AUTO- FILL process by pressing the BEGIN FILL Membrane Key.

Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ml	
Message Area	AUTO-FILL IN PROGRESS, PRESS ANY KEY TO STOP or msg. no. 16	
Membrane Keys 1-5	STOP or msg. no. 08	

5. ☐ Verify that Membrane Key 1 stops the Injector Ram.
6. Repeat steps 1 – 3 to invoke the AUTO- FILL process.
7. ☐ Verify that Membrane Key 2 stops the Injector Ram.
8. Repeat steps 1 – 3 to invoke the AUTO- FILL process.
9. ☐ Verify that Membrane Key 3 stops the Injector Ram.
10. Repeat steps 1 – 3 to invoke the AUTO- FILL process.
11. ☐ Verify that Membrane Key 4 stops the Injector Ram.
12. Repeat steps 1 – 3 to invoke the AUTO- FILL process.
13. ☐ Verify that Membrane Key 5 stops the Injector Ram.
14. Repeat steps 1 – 3 to invoke the AUTO- FILL process.
15. Tilt the Injector out of the LOAD position but not the RUN position.
16. ☐ Verify that tilting the Injector out of the LOAD position stops the Injector Ram.

17. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ML	
Message Area	TILT UP TO LOAD OR TILT DOWN TO RUN or msg. no. 09	
Membrane Key 1-5	N/A	

18. Tilt the Injector back to the LOAD position.

19. Repeat steps 1 – 3 to invoke the AUTO- FILL process.

20. Tilt the Injector to the RUN position.

21. ☐ Verify that tilting the Injector out of the LOAD position stops the Injector Ram.

22. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ML	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	▲	
Membrane Key 2	N/A	
Membrane Key 3	▼	
Membrane Key 4	EDA	
Membrane Key 5	N/A	

23. Tilt the Injector back to the LOAD position.

24. Repeat steps 1 – 3 to invoke the AUTO- FILL process. Set the Auto-Fill Volume = 95 ml.

25. ☐ Verify that the Injector volume displays approximately 95 ml.

26. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Verify Initials
Syringe Volume Indicator	XXX ml	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	▲	
Membrane Key 2	▲ ▲	
Membrane Key 3	▼	
Membrane Key 4	▼ ▼	
Membrane Key 5	Replace Syringe or msg. no. 01	

Section 4.4.2.9 of System Specification

Injector Configuration: Tilt Status: LOAD Position

Injector Ram Location: Between 1 and 200 ml

System Initialized and Loaded

Setup:

1. Using the arrow membrane keys, move the Injector Ram to a location somewhere between the 1 ml and 200 ml positions.

Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Verify Initials
Syringe Volume Indicator	XXX ml	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	▲	
Membrane Key 2	▲ ▲	
Membrane Key 3	▼	
Membrane Key 4	▼ ▼	
Membrane Key 5	Replace Syringe or msg. no. 01	

3. Press and hold Membrane Key 1.
4. ☐ Verify that Membrane Key 1 moves the Injector Ram forward at approximately 1 ml/sec.
5. Release Membrane Key 1.
6. ☐ Verify that when Membrane Key 1 is released the Injector Ram stops moving.
7. Press and hold Membrane Key 2.
8. ☐ Verify that Membrane Key 2 moves the Injector Ram forward at approximately 10 ml/sec.
9. Release Membrane Key 2.
10. ☐ Verify that when Membrane Key 2 is released the Injector Ram stops moving.
11. Press and hold Membrane Key 3.
12. ☐ Verify that Membrane Key 3 moves the Injector Ram reverse at approximately 0.5 ml/sec.
13. Release Membrane Key 3.
14. ☐ Verify that when Membrane Key 3 is released the Injector Ram stops moving.
15. Press and hold Membrane Key 4.
16. ☐ Verify that Membrane Key 4 moves the Injector Ram reverse at approximately 10 ml/sec.

17. Release Membrane Key 4.

18. ☐ Verify that when Membrane Key 4 is released the Injector Ram stops moving.

19. Press and hold Membrane Key 5 for at least one second. Release after at least one second.

20. ☐ Verify that Membrane Key 5 must be held at least for one second to initiate the REPLACE SYRINGE function (see Section 4.4.2.10).

21. ☐ Verify while Membrane Key 5 is held at least for one second that there is one short followed by one long acknowledgement tone and then the REPLACE SYRINGE function is initiated.

22. ☐ Verify that if Membrane Key 5 is held for less than one second the REPLACE SYRINGE function is not initiated.

23. Press any membrane key to stop the REPLACE SYRINGE function before it reaches the REPLACE SYRINGE position.

24. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Verify Initials
Syringe Volume Indicator	XXX ml	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	▲	
Membrane Key 2	▲ ▲	
Membrane Key 3	▼	
Membrane Key 4	▼ ▼	
Membrane Key 5	Replace Syringe or msg. no. 01	

25. Tilt the Injector out of the LOAD position but not in the RUN position.

26. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ML	
Message Area	TILT UP TO LOAD OR TILT DOWN TO RUN or msg. no. 09	
Membrane Key 1-5	N/A	

27. Tilt the Injector back to the LOAD position

28. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Verify Initials
Syringe Volume Indicator	XXX ml	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	▲	
Membrane Key 2	▲ ▲	
Membrane Key 3	▼	
Membrane Key 4	▼ ▼	
Membrane Key 5	Replace Syringe or msg. no. 01	

29. Use Membrane Key 2 to advance the Injector ram till it reaches 0 ml.

30. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	0 ML	
Message Area	PRESS AUTO-FILL OR RETRACT TO FILL SYRINGE or msg. no. 10	
Membrane Key 1	AUTO-FILL or msg. no. 11	
Membrane Key 2	N/A	
Membrane Key 3	▼	
Membrane Key 4	▼ ▼	
Membrane Key 5	REPLACE SYRINGE or msg. no. 01	

31. Use Membrane Key 3 to retract the Injector Ram till it reaches 10 ml.

32. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Verify Initials
Syringe Volume Indicator	XXX ml	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	▲	
Membrane Key 2	▲ ▲	
Membrane Key 3	▼	
Membrane Key 4	▼ ▼	
Membrane Key 5	Replace Syringe or msg. no. 01	

33. Use the Fast Reverse Key to bring the Injector Ram to the 200 ml position. Afterwards, use the Injector Hand knob to further retract the Injector Ram.

34. Confirm the following information is displayed:

Graphics Display Area	Displayed Information	Verify Initials
Syringe Volume Indicator	--- ml	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	Auto-Initialize or msg. no. 03	
Membrane Key 2	N/A	
Membrane Key 3	▲	
Membrane Key 4	▲ ▲	
Membrane Key 5	Replace Syringe or msg. no. 01	

35. Use the Injector Hand Knob to advance the Injector Ram until 200 ml is displayed.

36. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Verify Initials
Syringe Volume Indicator	200 ml	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 14	
Membrane Key 1	▲	
Membrane Key 2	▲ ▲	
Membrane Key 3	N/A	
Membrane Key 4	N/A	
Membrane Key 5	Replace Syringe or msg. no. 01	

Section 4.4.2.10 of system specification

Injector Configuration: Tilt Status: LOAD Position

Injector Ram Location: Between 0 and 200 ml

REPLACE SYRINGE invoked

Setup:

1. Move the Injector Ram to between the 1 ml and 200 ml position.
2. Press and hold Membrane Key 5 for at least one second. Release after at least one second.

Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ml	
Message Area	REPLACE SYRINGE IN PROGRESS, PRESS ANY KEY TO STOP or msg. no. 25	
Membrane Keys 1-5	STOP or msg. no. 08	

4. ☐ Verify that Membrane Key 1 stops the Injector Ram.
5. Restart the replace syringe process by depressing the REPLACE SYRINGE Membrane Key.
6. ☐ Verify that Membrane Key 2 stops the Injector Ram.
7. Restart the replace syringe process by depressing the REPLACE SYRINGE Membrane Key.
8. ☐ Verify that Membrane Key 3 stops the Injector Ram.
9. Restart the replace syringe process by depressing the REPLACE SYRINGE Membrane Key.
10. ☐ Verify that Membrane Key 4 stops the Injector Ram.
11. Restart the replace syringe process by depressing the REPLACE SYRINGE Membrane Key.
12. ☐ Verify that Membrane Key 5 stops the Injector Ram.
13. Restart the replace syringe process as described above.
14. Tilt the Injector out of the LOAD position but not in the RUN position.
15. ☐ Verify that tilting the Injector out of the LOAD position stops the Injector Ram.
16. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ML	
Message Area	TILT UP TO LOAD or TILT DOWN TO RUN or msg. no. 9	
Membrane Key 1-5	N/A	

17. Tilt the Injector back to the LOAD position.
18. Restart the replace syringe process as described above.
19. Tilt the Injector to the RUN position.
20. ☐ Verify that tilting the Injector to the RUN position stops the InjectorRam.

21. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ml	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	▲	
Membrane Key 2	N/A	
Membrane Key 3	▼	
Membrane Key 4	EDA	
Membrane Key 5	N/A	

20. Tilt the Injector back to the LOAD position.

21. Press and hold Membrane Key 5 to restart the Replace Syringe process. Allow the process to complete

22. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	— ML	
Message Area	PRESS AUTO-INITIALIZE OR MANUAL or msg. no. 02	
Membrane Key 1	AUTO-INITIALIZE or msg. no. 03	
Membrane Key 2	N/A	
Membrane Key 3	MANUAL or msg. no. 04	
Membrane Key 4	N/A	
Membrane Key 5	N/A	

23. Bring the Injector Ram to the 200 ml position. Press and hold Membrane Key 5 to restart the Replace Syringe process. Tilt the Injector out of the load position.

24. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	— ML	
Message Area	TILT UP TO LOAD or msg. no. 05	
Membrane Key 1-5	N/A	

25. Tilt the Injector back to the LOAD position.

26. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	--- ml	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	Auto-Initialize or msg. no. 03	
Membrane Key 2	N/A	
Membrane Key 3	▲	
Membrane Key 4	▲ ▲	
Membrane Key 5	Replace Syringe or msg. no. 01	

27. Restart the replace syringe process as described above. Allow the Replace Syringe function to complete.

Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	--- ML	
Message Area	PRESS AUTO-INITIALIZE OR MANUAL or msg. no. 02	
Membrane Key 1	Auto-Initialize or msg. no. 03	
Membrane Key 2	N/A	
Membrane Key 3	Manual or msg. no. 04	
MEMBRANE KEY 4	N/A	
Membrane Key 5	N/A	

Section 4.4.2.11 of system specification

Injector Configuration: Tilt Status: RUN Position or Between the LOAD and RUN Position
Injector Ram Location: Replace Syringe

Setup:

1. Place the Injector in the Replace Syringe position. Cycle power on the Injector.
2. Rotate the Injector to a position between the LOAD position and the RUN position.

Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	-- ML	
Message Area	TILT UP TO LOAD or msg. no. 05	
Membrane Key 1-5	N/A	

3. ☐ Verify that Membrane Key 1 is not active.
4. ☐ Verify that Membrane Key 2 is not active.
5. ☐ Verify that Membrane Key 3 is not active.
6. ☐ Verify that Membrane Key 4 is not active.
7. ☐ Verify that Membrane Key 5 is not active.
8. Open the syringe door.
9. ☐ Verify that the Injector now displays a syringe graphic with an arrow directing the door to be closed and the following message: "CLOSE DOOR" or msg. no. 17.
10. Close the syringe door.

SECTION 4.4.2.12 OF SYSTEM SPECIFICATION

Injector Configuration: Tilt Status: RUN Position

Injector Ram Location: Between 0 and 200 ml

Syringe loaded

Setup:

1. Press the MANUAL Membrane Key to place the Injector into manual mode.
2. Use the Arrow Membrane Keys to move the injector ram to a location that is approximately midway between the 0 ml and the 200 ml positions.
3. Rotate the Injector to the RUN position.

Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ml	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no.12	
Membrane Key 1	▲	
Membrane Key 2	N/A	
Membrane Key 3	▼	
Membrane Key 4	EDA	
Membrane Key 5	N/A	

3. Press and hold Membrane Key 1.
4. ☐ Verify that Membrane Key 1 moves the Injector Ram forward at approximately 1 ml/sec.
5. Release Membrane Key 1.
6. ☐ Verify that when Membrane Key 1 is released the Injector Ram stops moving.
7. ☐ Verify that Membrane Key 2 is not active.
8. Press and hold Membrane Key 3.
9. ☐ Verify that Membrane Key 3 retracts the Injector Ram forward at approximately 0.5 ml/sec.
10. Release Membrane Key 3.
11. ☐ Verify that when Membrane Key 3 is released the Injector Ram stops moving.
12. ☐ Verify that Membrane Key 4 toggles from Enabled and User-Disabled.
13. ☐ Verify that Membrane Key 5 is not active.
14. Press and hold the Injector Pendant switch.

15. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ML	
Message Area	CHECK OR RELEASE PENDANT or msg. no. 18	
Membrane Key 1-5	N/A	

16. Release the pendant switch.

17. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ml	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	▲	
Membrane Key 2	N/A	
Membrane Key 3	▼	
Membrane Key 4	EDA	
Membrane Key 5	N/A	

18. Tilt the Injector out of RUN BUT NOT IN LOAD position.

19. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ml	
Message Area	TILT UP TO LOAD OR TILT DOWN TO RUN or msg. no. 09	
Membrane Key 1-5	Not Active	

20. Tilt the Injector back to the RUN position.

Section 4.4.2.13 of system specification

INJECTOR CONFIGURATION: Tilt Status: Between the LOAD and RUN Position
Injector Ram Location: Between 0 and 200 ml
Syringe loaded

Setup:

1. Tilt the Injector to the LOAD position.
2. Use the Arrow Membrane Keys to move the injector ram to a location that is approximately midway between the 0 ml and the 200 ml positions.
3. Rotate the Injector to a position that is between the LOAD and RUN position (approximately horizontal).

Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ml	
Message Area	TILT UP TO LOAD OR TILT DOWN TO RUN or msg. no. 09	
Membrane Key 1-5	Not Active	

4. ☐ Verify that Membrane Keys 1 is Not Active.
5. ☐ Verify that Membrane Keys 2 is Not Active.
6. ☐ Verify that Membrane Keys 3 is Not Active.
7. ☐ Verify that Membrane Keys 4 is Not Active.
8. ☐ Verify that Membrane Keys 5 is Not Active.
9. Press and hold the Injector Pendant switch. Tilt the Injector to the RUN position.

10. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ML	
Message Area	CHECK OR RELEASE PENDANT or msg. no. 18	
Membrane Key 1-5	N/A	

11. Release the Injector Pendant Switch.
12. Tilt the Injector to the LOAD position. Advance the Injector ram to the 0 ml position. Tilt the Injector to the RUN position. Cycle power off and then on to the Injector.

13. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	0 ml	
Message Area	TILT UP TO LOAD or msg. no 05	
Membrane Key 1-5	Not Active	

Section 4.4.2.14 of system specification

Injector Configuration: Tilt Status: RUN Position

Injector Ram Location: Between 1 and 200 ml
Syringe loaded

Setup:

1. Program a one valid phase into the Remote Control.
2. ☐ Verify that the EDA is IN RANGE and there is a stable baseline.
3. ☐ Verify that the Injector is tilted into the RUN position.
4. ☐ Verify that the Injector Ram is between 1 and 200 ml.
5. ☐ Verify that the Remote Control is in the STOP Mode Main Menu Screen.
6. ☐ Verify that there has been no Remote activity for two or more seconds.
7. ☐ Verify that the message "Injector Not Found" or "Remote Not Found" are not displayed.
8. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ML	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM PRESS ARM TO CONTINUE or msg. no. 19	
Membrane Key 1	▲	
Membrane Key 2	N/A	
Membrane Key 3	▼	
Membrane Key 4	EDA	
Membrane Key 5	ARM or msg. no. 20	

9. Press and hold Membrane Key 1.
10. ☐ Verify that Membrane Key 1 moves the Injector Ram forward at approximately 1 ml/sec.
11. Release Membrane Key 1.
12. ☐ Verify that when Membrane Key 1 is released the Injector Ram stops moving.
13. ☐ Verify that Membrane Key 2 is not active.
14. Press and hold Membrane Key 3.
15. ☐ Verify that Membrane Key 3 moves the Injector Ram backward at approximately 0.5 ml/sec.
16. Release Membrane Key 3.

17. ☐ Verify that when Membrane Key 3 is released the Injector Ram stops moving.

18. Press Membrane Key 4.

19. ☐ Verify that when Membrane Key 4 is pressed once that the EDA displays "EDA USER-DISABLED" or msg. no. 21.

20. Press Membrane Key 4 again.

21. ☐ Verify that when Membrane Key 4 is pressed once that the EDA displays "EDA ENABLED – IN RANGE" or msg. no. 22 after a five seconds of pressing the key.

22. Press and hold Membrane Key 1.

23. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ml	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	▲	
Membrane Key 2	N/A	
Membrane Key 3	▼	
Membrane Key 4	EDA	
Membrane Key 5	N/A	

24. Release Membrane Key 1.

25. Wait two seconds and confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ML	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM PRESS ARM TO CONTINUE or msg. no. 19	
Membrane Key 1	▲	
Membrane Key 2	N/A	
Membrane Key 3	▼	
Membrane Key 4	EDA	
Membrane Key 5	ARM or msg. no. 20	

26. Press and hold Membrane Key 3.

27. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ml	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	▲	
Membrane Key 2	N/A	
Membrane Key 3	▼	
Membrane Key 4	EDA	
Membrane Key 5	N/A	

28. Release Membrane Key 3.

29. Wait two seconds and confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ML	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM PRESS ARM TO CONTINUE or msg. no. 19	
Membrane Key 1	▲	
Membrane Key 2	N/A	
Membrane Key 3	▼	
Membrane Key 4	EDA	
Membrane Key 5	ARM	

30. Press and hold the Injector Pendant switch.

31. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ML	
Message Area	CHECK OR RELEASE PENDANT or msg. no. 18	
Membrane Key 1-5	N/A	

32. Release the pendant switch.

33. Wait two seconds and confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ML	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM PRESS ARM TO CONTINUE or msg. no. 19	
Membrane Key 1	▲	
Membrane Key 2	N/A	
Membrane Key 3	▼	
Membrane Key 4	EDA	
Membrane Key 5	ARM or msg. no. 20	

34. Press the Program or msg. no. 23 key.

35. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ml	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	▲	
Membrane Key 2	N/A	
Membrane Key 3	▼	
Membrane Key 4	EDA	
Membrane Key 5	N/A	

36. Press the Return Key on the Remote. Wait for two seconds. Confirm the following is displayed.

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ML	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM PRESS ARM TO CONTINUE or msg. no. 19	
Membrane Key 1	▲	
Membrane Key 2	N/A	
Membrane Key 3	▼	
Membrane Key 4	EDA	
Membrane Key 5	ARM or msg. no. 20	

37. Disconnect the Remote communications cable at the power supply end.

38. ☐ Verify that when message "Remote Not Found" or msg. no. 24 is displayed on the Injector.

39. Confirm that the following is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ml	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM or msg. no. 12	
Membrane Key 1	▲	
Membrane Key 2	N/A	
Membrane Key 3	▼	
Membrane Key 4	N/A	
Membrane Key 5	N/A	

40. Reconnect the Remote communications cable at the power supply end.

41. ☐ Verify that when message "Remote Not Found" or msg. no. 24 is removed from the Injector display.

42. Wait for two seconds and confirm the following is displayed.

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ML	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM PRESS ARM TO CONTINUE or msg. no. 19	
Membrane Key 1	▲	
Membrane Key 2	N/A	
Membrane Key 3	▼	
Membrane Key 4	EDA	
Membrane Key 5	ARM	

43. Tilt the Injector out of RUN but not in load position.

44. Confirm that the following information is displayed:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ml	
Message Area	TILT UP TO LOAD OR TILT DOWN TO RUN or msg. no. 09	
Membrane Key 1-5	Not Active	

45. Tilt the Injector back to the RUN position.

46. Wait for two seconds and confirm the following is displayed.

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ML	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM PRESS ARM TO CONTINUE or msg. no. 19	
Membrane Key 1	▲	
Membrane Key 2	N/A	
Membrane Key 3	▼	
Membrane Key 4	EDA	
Membrane Key 5	ARM or msg. no. 20	

47. Start a stopwatch. DO NOT TOUCH ANY KEY ON THE INJECTOR OR REMOTE FOR APPROXIMATELY 30 MINUTES.

48. ☐ Verify that after approximately 30 minutes, the Injector displays a screen saver with the following information: "EZEM EmpowerCT".

49. ☐ Verify that pressing any key turns the screen saver off and that the Injector displays the following:

Graphics Display Area	Displayed Information	Initials
Syringe Volume Indicator	XXX ML	
Message Area	WARNING: PURGE ALL AIR FROM SYSTEM PRESS ARM TO CONTINUE or msg. no. 19	
Membrane Key 1	▲	
Membrane Key 2	N/A	
Membrane Key 3	▼	
Membrane Key 4	EDA	
Membrane Key 5	ARM or msg. no. 20	

50. Tilt the Injector up. Press the Replace Syringe key or message no. 1 key. Allow the Replace syringe to be completed. Repower the Injector.

51. Start a stopwatch. DO NOT TOUCH ANY KEY ON THE INJECTOR OR REMOTE FOR APPROXIMATELY 30 MINUTES.

52. ☐ Verify that after approximately 30 minutes, the Injector displays a screen saver with the following information: "EZEM EmpowerCT".

53. ☐ Verify that pressing any key turns the screen saver off.

Burn-In Mode (test to be performed in English only)

For all other languages, change system back to English for testing purposes

1. Power off the Injector.
2. Press and hold membrane Key 1 and Key 3. Turn the Injector On.
3. ☐ Verify that after approximately five seconds that the Injector ram begins to move.
4. ☐ Verify that when the Injector Ram is moving at approximately 5 ml/sec.
5. ☐ Verify that the Injector display has an area from Burn cycles and that it is initially equal to zero.
6. Tilt the Injector into the three tilt positions.
7. ☐ Verify that tilting the Injector does not stop the Burn-In Mode.
8. Press any of the membrane keys.
9. ☐ Verify that pressing any membrane key does not stop the Burn-In Mode.
10. Allow the Injector ram to advance to the 0 ml position.
11. ☐ Verify that after the Injector ram reaches the 0 ml position, the Injector ram starts to retract.
12. ☐ Verify that when the Injector Ram is moving at approximately 5 ml/sec.
13. Allow the injector ram to retract to the Replace syringe position.
14. ☐ Verify that after the Injector ram reaches 0 ml position, the burn-in cycle is incremented.

Software Compatibility Testing: This test applies to software release 2.04a and higher

1. Power on an EmpowerCT Injector, EDA and Remote system with the software revision and language as stated on page 3 of this test plan.
2. ☐ Verify that the system does not display "Injector Not Found", "EDA Not Found" and "Remote Not Found".
3. ☐ Verify that the system is able to perform an injection.
4. Power off the Injector only.
5. Power on the second system. Change the Remote language to another language beside the language tested on page of the test plan. Power off the second Remote Control.
6. Disconnect the first Remote Control and attach the second Remote Control. Power on the system.
7. Utilize the table to verify that the Injector and Remote display the message listed in matrix in their appropriate language and that the system cannot be armed with the mismatch. Complete the matrix. Note for case where the Injector and Remote language are the same, tester to write N/A in the table for the verification steps. Repower Injector each language check. Note the Injector language message will be same for each part of this test.

Injector Language from Page 3 (user writes down language)	Remote Language	Injector Language Mismatch Message	Language Mismatch Message	Initial that Messages are correct	Initial that system can not be armed
	English	Language Mismatch	Language Mismatch, Please Select Desired Language.		
	German	Language MismatchG	Falsche Sprache, bitte gewünschte Sprache wählen		
	Italian	Language MismatchI	Errore di lingua, scegliere la lingua desiderata		
	French	Language MismatchF	Discordance de langue, Choisissez la langue souhaitée		
	Portuguese	Language MismatchP	Erro de idioma. Seleccione idioma desejado.		
	Spanish	Language MismatchS	Idioma incorrecto. Seleccione idioma deseado		

8. After the testing is completed, power off the Remote. Connect a Remote with software release 01.03a to the system. Power on the system.

9. Utilize the table to verify that the Injector and Remote will not allow the system to arm if the Injector is in a language beside English and the remote is software release 01.03a.

Injector Language from Page 3 (user writes down language)	Remote Language (software release 01.03a)	Initial that system can not be armed
	English	

10. Attach an English Injector software release 2.04a or later and the Remote software release 01.03a.
11. ☐ Verify that the system is able to perform an injection.

LANGUAGE MESSAGE TRANSLATION

Msg #	MESSAGE AREA	GERMAN	ITALIAN	PORTUGUESE	FRENCH	SPANISH
1	REPLACE SYRINGE	SPRITZE AUSWECHSELN	SOSTITUIRE SIRINGA	SUBSTITUIR SERINGA	REEMPLACER LA SERINGUE	SUSTITUIR JERINGUILLA
2	PRESS AUTO-INITIALIZE OR MANUAL	AUTO-INITIALISIERUNG ODER MANUELL DRUCKEN	PREMERE AUTO INIZIALIZZA O MANUALE	PRIMA INICIALIZACAO AUTOMATICA OU MANUAL	APPUYER SUR AUTO-INITIALISER OU MANUEL	PULSE INICIO AUTOMATICO O MANUAL
3	AUTO INITIALIZE	AUTO-INITIALISIERUNG	AUTO INIZIALIZZA	INICIALIZACAO AUTOMATICA	AUTO INITIALISER	AUTOINICIO
4	MANUAL	MANUELL	MANUALE	MANUAL	MANUEL	MANUAL
5	TILT UP TO LOAD	ZUM LADEN NACH OBEN KIPPEN	INCLINARE IN SU PER CARICARE	VOLTAR PARA CIMA PARA CARREGAR	TOURNER VERS LE HAUT POUR CHARGER	BASCULE HACIA ARRIBA PARA CARGAR
6	PRESS AUTO INITIALIZE OR MANUAL OR REPLACE SYRINGE	AUTO-INITIALISIERUNG ODER MANUELL ODER SPRITZE AUSWECHSELN DRUCKEN	PREMERE AUTO INIZIALIZZA O MANUALE O SOSTITUIRE SIRINGA	PRIMA INICIALIZACAO AUTOMATICA OU MANUAL OU SUBSTITUIR SERINGA	APPUYER SUR AUTO-INITIALISER OU MANUEL OU REMPLACER LA SERINGUE	PULSE INICIO AUTOMATICO O MANUAL O SUSTITUIR JERINGUILLA
7	AUTO INITIALIZATION IN PROGRESS, PRESS ANY KEY TO STOP	AUTO-INITIALISIERUNG LAUFT, ZUM STOPPEN BELIEBIGE TASTE DRUCKEN	AUTO INIZIALIZZAZIONE IN CORSO, PREMERE UN TASTO PER INTERROMPERE	INICIALIZACAO AUTOMATICA EM CURSO, PRIMA QUALQUER TECLA PARA PARAR	AUTO-INITIALISATION EN COURS, APPUYER SUR UNE TOUCHE POUR ARRETER	INICIO AUTOMATICO EN MARCHA, PULSE CUALQUIER TECLA PARA DETENER
8	STOP	STOPP	STOP	PARAR	STOP	DETENER
9	TILT UP TO LOAD OR TILT DOWN TO RUN	ZUM LADEN NACH OBEN, ZUR AUSFUHRUNG NACH UNTEN KIPPEN	INCLINARE IN SU PER RIEMPIRE O IN GIU PER ESEGUIRE IL CICLO	VOLTAR PARA CIMA PARA CARREGAR OU PARA BAIXO PARA EXECUTAR	TOURNER VERS LE HAUT POUR CHARGER OU VERS LE BAS POUR INJECTER	BASCULE HACIA ARRIBA PARA CARGAR O HACIA ABAJO PARA EJECUTAR
10	PRESS AUTO-FILL OR RETRACT TO FILL SYRINGE	AUTO-FULLUNG ODER RUCKZUG DRUCKEN, UM DIE SPRITZE ZU FULLEN	PREMERE AUTO RIEMPIMENTO O RETRARRE PER RIEMPIRE SIRINGA	PRIMA ENCHIMENTO AUTOMATICO OU RETRAIA PARA ENCHER SERINGA	APPUYER SUR REMPLISSAGE AUTO OU RETRACTER POUR REMPLIR LA SERINGUE	PULSE RELLENO AUTOMATICO O RETIRAR PARA LLENAR JERINGUILLA
11	AUTO FILL	AUTO-FULLUNG	AUTO RIEMPIMENTO	ENCHIMENTO AUTOMATICO	REPLISSAGE AUTO	AUTORELLENO
12	WARNING: PURGE ALL AIR FROM SYSTEM	WARNUNG: SYSTEM KOMPLETT ENTLUFTEN	AVVISO: EVACUARE TUTTA L'ARIA DAL SISTEMA	AVISO: EXTRAIA TODO O AR DO SISTEMA	AVERTISSEMENT: PURGER L'AIR DU SYSTEME	ADVERTENCIA: ELIMINE TODO EL AIRE DEL SISTEMA
13	FILL VOL. = XXX ML, PRESS ADD 5 OR ADD 25 TO INCREMENT. PRESS BEGIN AUTO-FILL TO START.	FULLVOL. = XXXML, INKREM MIT 5 ODER 25 HINZUF AUTO-FULL ZUM STARTEN.	VOL RIEMP = XXXML, PREM AGG 5 O AGG 25 PER AUMENTARE. INIZIO AUTORIEMP PER COMINCIARE..	ENCH AUTO = XXXML, PRIMA +5 OU +25 P/ INCREMENTAR. PRIMA 'INICIAR ENCH.' PARA COMECAR.	VOL REMPL=XXX ML APP SUR AJOUT 5 OU AJOUT 25 PR INCREM. APP SR COMMENC AUTO REMPL POUR DEMARRER	LLENAR VOL = XXXml., PULS. +5/+25 PARA AUMENTAR PULS. INI. AUTORELLENO PARA COMENZAR
14	BEGIN FILL	FULLUNG BEGINNEN	INIZIO RIEMPIMENTO	INICIAR ENCHIMENTO	COMMENC REMLIS	INICIAR RELLENO
15	CANCEL	ABBRECHEN	ANNULLA	CANCELAR	ANNULER	ANULAR
16	AUTO FILL IN PROGRESS, PRESS ANY KEY TO STOP	AUTO-FULLUNG LAUFT, ZUM STOPPEN BELIEBIGE TASTE DRUCKEN	AUTO RIEMPIMENTO IN CORSO, PREMERE UN TASTO PER INTERROMPERE	ENCHIMENTO AUTOMATICO EM CURSO, PRIMA QUALQUER TECLA PARA PARAR	REPLISSAGE AUTO EN COURS, APPUYER SUR UNE TOUCHE POUR ARRETER	RELLENO AUTOMATICO EN MARCHA, PULSE CUALQUIER TECLA PARA DETENER
17	CLOSE DOOR	TUR SCHLIESSEN	CHIUDERE SPORTELLLO	FECHAR PORTA	FERMER LA PORTE	CIERRE ORIFICIO DE ENTRADA
18	CHECK OR RELEASE PENDANT	HANDSCHALTER PRUFEN BZW. FREIGEBEN	CONTROLLARE O RILASCIARE LA PULSANTIERA	VERIFICAR OU LIBERTAR COMUTADOR	VERIFIEZ OU RELACHEZ L'INTERRUPTEUR INJECT./PAUSE	COMPRUEBE O LIBERE EL COLGANTE

Msg #	MESSAGE AREA	GERMAN	ITALIAN	PORTUGUESE	FRENCH	SPANISH
19	WARNING: PURGE ALL AIR FROM SYSTEM, PRESS ARM TO CONTINUE	WARNUNG: SYSTEM KOMPLETT ENTLUFTEN, DANN BEREIT DRUCKEN, UM FORTZUFAHREN	AVVISO: EVACUARE TUTTA L'ARIA DAL SISTEMA, PREMERE CARICA PER CONTINUARE	AVISO: EXTRAIA TODO O AR DO SISTEMA, PRIMA ARMAR PARA CONTINUAR	AVERTISSEMENT: PURGER L'AIR DU SYSTEME, APPUYER SUR ARMER POUR CONTINUER	ADVERTENCIA: ELIMINE TODO EL AIRE DEL SISTEMA, PULSE ARMAR PARA CONTINUAR
20	ARM	BEREIT	CARICA	ARMAR	ARMER	ARMAR
21	EDA USER- DISABLED	EDA DEAKTIVIERT	UTENTEEDA DISATTIVATO	EDA DESAC POR UTIL.	EDA DÉS. PAR UTIL.	EDA DESAC P USARIO
22	EDA IN RANGE	EDA IM BEREICH	EDA IN RANGE	EDA DENTRO LIM	EDA DANS PLAGE	EDA EN ESCALA
23	PROGRAM	PROGR.	PROGRAM	PROGRAM	PROGRAM	PROGRAM
24	REMOTE NOT FOUND	FERNSTEUERUNG NICHT GEFUNDEN	TELECOMANDO NON TROVATO	TELECOMANDO NÃO ENCONTRADO	TELECOMANDE INTROUVABLE	REMOTO NO ENCONTRADO
25	REPLACE SYRINGE IN PROGRESS, PRESS ANY KEY TO STOP	SPRITZE WIRD GEWECHSELT, ZUM STOPPEN BELIEBIGE TASTE DRUCKEN	SOSTITUZIONE SIRINGA IN CORSO, PREMERE UN TASTO PER INTERROMPERE	SUBSTITUIR A SERINGA EM CURSO, PRIMA QUALQUER TECLA PARA PARAR	REEMPLACER LA SERINGUE EN COURS, APPUYER SUR UNE TOUCHE POUR ARRETER	SUSTITUIR JERINGUILLA EN MARCHA,PULSE CUALQUIER TECLA PARA DETENER

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